

**4002. Misbranding of pentobarbital sodium capsules, Dexedrine Sulfate tablets, and capsules containing dextro-amphetamine sulfate plus minerals and vitamins. U. S. v. Paramount Drug Co. Plea of nolo contendere. Fine, \$25. (F. D. C. No. 32701. Sample Nos. 20763-L, 20795-L, 21417-L to 21420-L, incl., 22265-L, 22267-L.)**

**INFORMATION FILED:** March 31, 1953, Middle District of Alabama, against the Paramount Drug Co., Montgomery, Ala.

**NATURE OF CHARGE:** On or about February 6 and May 3 and 4, 1951, while a number of *pentobarbital sodium capsules* and *Dexedrine Sulfate tablets* were being held for sale at the Paramount Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded as follows: Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), a portion of the repackaged *Dexedrine Sulfate tablets* failed to bear a label containing the common or usual name of each active ingredient of the drug; and, Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use.

On January 7 and 9, 1953, while a number of *capsules containing dextro-amphetamine sulfate plus minerals and vitamins* were being held for sale at the Paramount Drug Co., after shipment in interstate commerce, the defendant caused a number of the capsules to be dispensed without a prescription from a practitioner licensed by law to administer such drug. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drug being misbranded.

**DISPOSITION:** March 31, 1953. The defendant having entered a plea of nolo contendere, the court fined it \$25.

#### **DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\***

**4003. Misbranding of pentobarbital sodium capsules. U. S. v. Roy C. Holcomb (Holcomb Drug Store), and Adolph T. Stava. Plea of nolo contendere by Defendant Holcomb and plea of guilty by Defendant Stava. Fine of \$50, plus costs, against Defendant Holcomb and \$50 against Defendant Stava. (F. D. C. No. 33748. Sample Nos. 16242-L, 16243-L.)**

**INFORMATION FILED:** January 21, 1953, District of Nebraska, against Roy C. Holcomb, trading as the Holcomb Drug Store, Broken Bow, Nebr., and Adolph T. Stava, a pharmacist.

**ALLEGED VIOLATION:** On or about March 28 and 31, 1952, while a number of *pentobarbital sodium capsules* were being held for sale at the Holcomb Drug Store, after shipment in interstate commerce, the defendants caused a number of the capsules to be repacked and dispensed without a prescription, which acts resulted in the repackaged capsules being misbranded.

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\*See also Nos. 4001, 4002.

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use.

**DISPOSITION:** April 3, 1953. A plea of nolo contendere having been entered by Defendant Holcomb and a plea of guilty by Defendant Stava, the court fined Defendant Holcomb \$50, plus costs, and Defendant Stava \$50.

**4004. Misbranding of pentobarbital sodium capsules and amphetamine sulfate tablets. U. S. v. Jacob Marcus (Shawmut Pharmacy). Plea of guilty. Fine of \$500 and sentence of 6 months in jail; jail sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 33798. Sample Nos. 6135-L to 6137-L, incl., 6140-L, 6187-L, 6192-L, 6194-L, 6277-L.)**

**INFORMATION FILED:** February 5, 1953, District of Massachusetts, against Jacob Marcus, trading as the Shawmut Pharmacy, Boston, Mass.

**ALLEGED VIOLATION:** On October 29 and 31 and November 10, 12, and 13, 1951, while a number of *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were being held for sale at the Shawmut Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a physician's prescription, which acts resulted in the drugs so dispensed being misbranded.

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the dispensed drugs failed to bear adequate directions for use; and, Sections 502 (b) (1) and (2), the *pentobarbital sodium capsules* and a portion of the *amphetamine sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the *amphetamine sulfate tablets* failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the *amphetamine sulfate tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

**DISPOSITION:** May 18, 1953. The defendant having entered a plea of guilty, the court fined him \$500 and sentenced him to serve 6 months in jail. The jail sentence was suspended, and the defendant was placed on probation for 2 years.